

IFW

PTO/SB/21 (01-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/687,677	
	Filing Date	10/17/2003	
	First Named Inventor	GUY	
	Art Unit	1642	
	Examiner Name		
Total Number of Pages in This Submission	114	Attorney Docket Number	5853-324

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Certified Copy of Priority Document(s)	Remarks	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application	No fees are believed necessary, but please charge any deficiencies to Deposit Account No. 50-0951.	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual	AKERMAN SENTERFITT Gregory A. Nelson, Registration No. 30,577
Signature	
Date	8-5-04

CERTIFICATE OF TRANSMISSION/MAILING	
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: _____	
Typed or printed	Gregory A. Nelson
Signature	
Date	8-5-04

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of GUY

Application No. 10/687,677

Examiner:

Filed: October 17, 2003

Group Art Unit: 1642

For: REDUCING CELLULAR DYSFUNCTION CAUSED BY MITOCHONDRIAL GENE  
MUTATIONS

**INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR §1.97(b)**

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile  
transmitted to the USPTO or deposited with the United States Postal  
Service with sufficient postage as first class mail in an envelope  
addressed to: Commissioner for Patents, Alexandria, VA  
22313-1450 on 8-5-94

Gregory A. Nelson

Reg. No. 30,577

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the Duty to Disclose under 37 C.F.R. §1.56, the references cited on the accompanying form PTO/SB/08A are hereby brought to the attention of the Examiner for independent evaluation. The references were cited in the specification of the present application.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

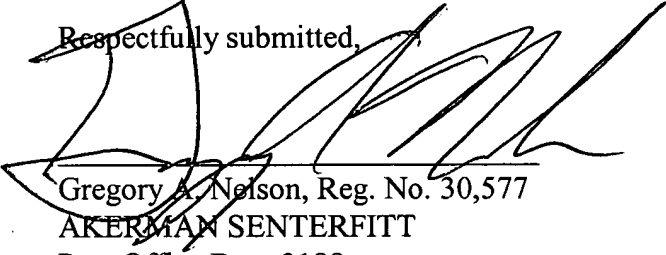
Applicant respectfully requests that the listed documents be considered by the Examiner and made of record in the present application and that an initialed copy of form PTO/SB/08A be returned in accordance with MPEP §609.

Certification

This Statement is being filed within three months of the filing of this application and/or prior to the issuance of the first Office Action for the present application, and this paper is thus submitted in accordance with 37 CFR §1.97(b). In view of this certification, a fee is not required for consideration of these documents. Nevertheless, should a fee be deemed to be due by the Commissioner, such fee should be charged to Deposit Account No. 50-0951.

Dated: 8-5-04

Respectfully submitted,



Gregory A. Nelson, Reg. No. 30,577  
AKERMAN SENTERFITT  
Post Office Box 3188  
West Palm Beach, FL 33402-3188  
Telephone: (561) 653-5000

Docket No. 5853-324



PTO/SB/08B (02-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/687,677
		Filing Date	10/17/2003
		First Named Inventor	GUY
		Art Unit	1642
		Examiner Name	
Sheet 1	of 2	Attorney Docket Number	5853-324

OTHER PRIOR ART–NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Larsson NG, Andersen O, Holme E et al. Leber's hereditary optic neuropathy and complex I deficiency in muscle. Ann Neurol. 1991; 30:701-708	
		Majander A, Huoponen K, Savontaus ML et al. Electron transfer properties of NADH:ubiquinone reductase in the ND1/3460 and the ND4/11778 mutations of the Leber hereditary optic neuroretinopathy (LHON). FEBS Lett. 1991; 292:289-292	
		Vergani L, Martinuzzi A, Carelli V et al. MtDNA mutations associated with Leber's hereditary optic neuropathy: studies on cytoplasmic hybrid (cybrid) cells. Biochem Biophys Res Commun. 1995; 210:880-888	
		Wallace DC. Mitochondrial diseases in man and mouse. Science. 1999; 283:1482-1488	
		Carelli V, Ghelli A, Bucchi L et al. Biochemical features of mtDNA 14484 (ND6/M64V) point mutation associated with Leber's hereditary optic neuropathy. Ann Neurol. 1999; 45:320-328	
		Chinnery PF, Johnson MA, Wardell TM et al. The epidemiology of pathogenic mitochondrial DNA mutations. Ann Neurol. 2000; 48:188-193	
		Guy J, Qi X, Hauswirth WW. Adeno-associated viral-mediated catalase expression suppresses optic neuritis in experimental allergic encephalomyelitis. Proc Natl Acad Sci U S A. 1998; 95:13847-13852	
		Wallace DC, Singh G, Lott MT et al. Mitochondrial DNA mutation associated with Leber's hereditary optic neuropathy. Science. 1988; 242:1427-1430	
		Hartl FU, Neupert W. Protein sorting to mitochondria: evolutionary conservations of folding and assembly. Science. 1990; 247:930-938	
		Schon EA. Mitochondrial genetics and disease. Trends Biochem Sci. 2000; 25:555-560	

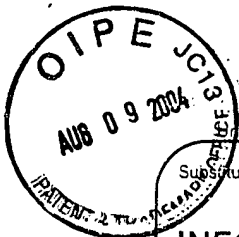
Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (02-03)

Approved for use through 04/30/2003. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/687,677
Filing Date	10/17/2003
First Named Inventor	GUY
Art Unit	1642
Examiner Name	
Attorney Docket Number	5853-324

Sheet	2	of	2
-------	---	----	---

**OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Guy J, Qi X, Muzyczka N et al. Reporter expression persists 1 year after adeno-associated virus- mediated gene transfer to the optic nerve. Arch Ophthalmol. 1999; 117:929-937	
		Esposito LA, Melov S, Panov A et al. Mitochondrial disease in mouse results in increased oxidative stress. Proc Natl Acad Sci U S A. 1999; 96:4820-4825	
		Brown MD, Trounce IA, Jun AS et al. Functional analysis of lymphoblast and cybrid mitochondria containing the 3460, 11778, or 14484 Leber's hereditary optic neuropathy mitochondrial DNA mutation. J Biol Chem. 2000; 275:39831-39836	
		Brown MD. The enigmatic relationship between mitochondrial dysfunction and Leber's hereditary optic neuropathy. J Neurol Sci. 1999; 165:1-5	
		Cock HR, Cooper JM, Schapira AH. Functional consequences of the 3460-bp mitochondrial DNA mutation associated with Leber's hereditary optic neuropathy. J Neurol Sci. 1999; 165:10-17	
		Sazanov, L. Resolution of the Membrane Domain of Bovine Complex I into Subcomplexes: Implications for the Structural Organization of the Enzyme. Biochemistry 2000, 39: 7229-7235	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.